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LEGAL DEPARTMENT

FAX NUMBERS (650) 952-9881 or (650) 952-9882

DATE: December 10, 2003

Please deliver the following page(s) to:

Name: Office of Petitions
Firm: United States Patent and Trademark Office
Fax: (703) 872-9306
From: David W Evans*
Genentech, Inc.
One DNA Way, So. SF CA. 94080
(650) 225-1732 Phone
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NUMBER OF PAGES INCLUDING THIS COVER SHEET: 20

CONFIDENTIALITY NOTE

The documents accompanying this facsimile transmission contain information from GENENTECH, INC. which is confidential or privileged. This information is intended only for the individual or entity named on this transmission sheet. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this faxed information is strictly prohibited. If you have received this facsimile in error, please notify us by telephone immediately so that we can arrange for the return of the original documents to us and the retransmission of them to the intended recipient.

COMMENTS:

Re: USSN 10/649,762
Filed 26 August 2003
Confirmation No.: 7341

IF YOU DID NOT RECEIVE ALL OF THE PAGES, PLEASE CALL AIDA GULAM AS SOON AS POSSIBLE AT (650) 225-1732.

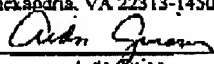
* A copy of a document pursuant to 37 C.F.R. §10.9(b) is attached as proof of the authorization of the above to prosecute the attached application. The original of this document is on file in the Office of Enrollment and Discipline.

OFFICIAL

Patent Docket P13655R2C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**RECEIVED
CENTRAL FAX CENTER****DEC 10 2003**

In re Application of Burdick et al. Serial No.: 10/649,762 Filed: 26 August 2003 For: ANTAGONISTS FOR TREATMENT OF CD11/CD18 ADHESION RECEPTOR MEDIATED DISORDERS	Group Art Unit: Examiner: Confirmation No. 7341 Customer No. 09157 CERTIFICATE OF FACSIMILE TRANSMISSION <u>December 10, 2003</u> Date of Transmission I hereby certify that this correspondence, consisting of Petition, is being facsimile transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.  Aida Guian
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PETITION UNDER 37 C.F.R. §1.181(f) AND/OR §1.182

Attention: Office of Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned hereby petitions the Director to accord a filing date of August 26, 2003 for the captioned application (the date originally deposited) and to accept Figures 1 through 5, (copies attached hereto) as part of the application as filed. The Director is hereby authorized to deduct the appropriate fee of \$130 set forth in 37 C.F.R. §1.17(h) associated with this petition (and charge any other fee that may be due or credit any overpayment) to Deposit Account No. 07-0630.

Statement of Facts

1. The captioned application was filed on August 26, 2003, as a continuation under 37 C.F.R. §1.53(b) of prior application serial no. 09/646,330 filed September 14, 2000.

U.S. Serial No.: 10/649,762
Patent Docket P1365R2C1
Page 2

2. The transmittal document of the captioned application states that the specification and drawings are identical to the specification and drawings of parent application 09/646,330 as filed on September 14, 2000. However, the application papers deposited with the Office in fact omitted copies of Figures 1-5 from the parent application.
3. The transmittal document of the captioned application states that the present application incorporates by reference the entire disclosure of the parent application 09/646,330.
4. The captioned application in the first paragraph (page 1, lines 4-8) incorporates by reference the entire disclosure of the parent application 09/646,330.
5. Apart from the omission of Figures 1-5, the captioned application is in fact a true copy of the parent application as filed. In particular, the specific descriptions of Figures 1-5 remain at pages 22-23 of the captioned application.
6. The Declaration under 37 C.F.R. §1.63 filed with the captioned application is a true copy of the original declaration executed by the inventors for the parent application 09/646,330.
7. The omission of original Figures 1-5 in the captioned application was noted by the OIPE in its "Notice Of Incomplete Nonprovisional Application" mailed November 17, 2003 which set a two month deadline to respond.

Discussion

Figures 1-5 were omitted from the captioned application papers deposited August 26, 2003 solely through clerical error. The following facts indicate that Applicants had no intention of filing an amended or redacted specification. First, Applicants' representative stated in good faith (albeit erroneously), that the captioned application was a complete copy of the parent application. Second, the transmittal and specification of the captioned application both state that the entire disclosure of parent application 09/646,330 (which includes Figures 1-5) is incorporated by reference. Third, the §1.63 Declaration executed by the inventors and relied upon in the captioned application refers to the complete parent application filed as serial no. 09/646,330 (*i.e.*, including Figures 1-5).

U.S. Serial No.: 10/649,762
Patent Docket P1365R2C1
Page 3

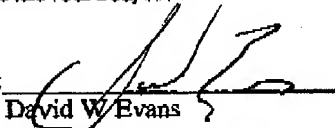
Applicants believe that omitted Figures 1-5 should be considered as having been filed with the captioned application as deposited on August 26, 2003. Both the transmittal document and the specification (page 1, lines 4-8) specifically incorporate by reference the parent application in its entirety (including Figures 1-5). Copies of the transmittal and page 1 of the specification are enclosed herewith. Furthermore, Applicants do not believe the omitted Figures 1-5 are essential to describing the invention in the manner required by 35 U.S.C. § 112. Accordingly, should the Director not accept Figures 1-5 as having been originally filed, the captioned application is nevertheless entitled to a filing date of August 26, 2003, the date originally deposited.

Request for Relief

For the reasons set forth above, Applicants respectfully petition the Director to accord a filing date of August 26, 2003 for the captioned application, the date originally deposited. The Director is hereby authorized to deduct the appropriate fee of \$130 associated with this petition (and charge any other fee that may be due or credit any overpayment) to Deposit Account No. 07-0630.

Respectfully submitted,
GENENTECH, INC.

Date: December 10, 2003

By: 
David W. Evans
Reg. No. *
Telephone No. (650) 225-1739

Enclosures:

- copies of as-filed pages of Figures 1-5 from the parent application
- copy of application transmittal
- copy of page 1 of captioned application

* A copy of a document pursuant to 37 C.F.R. §101.9(b) is attached as proof of the authorization of the above to prosecute the attached application. The original of this document is on file in the Office of Enrollment and Discipline.



UNITED STATES PATENT AND TRADEMARK OFFICE

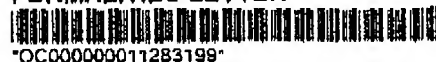
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/649,762	08/26/2003	Daniel J. Burdick	P1365R2C1

09157
GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

CONFIRMATION NO. 7341

FORMALITIES LETTER



OC000000011283199

Date Mailed 11/17/2003

NOTICE OF INCOMPLETE NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has NOT been accorded to the above-identified application papers for the reason(s) indicated below

All of the items noted below and a newly executed oath or declaration covering the items must be submitted within **TWO MONTHS** of the date of this Notice, unless otherwise indicated, or proceedings on the application will be terminated (37 CFR 1.53(e)). Replies should be mailed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450

The filing date will be the date of receipt of all items required below, unless otherwise indicated. Any assertions that the item(s) required below were submitted, or are not necessary for a filing date, must be by way of petition directed to the attention of the Office of Petitions accompanied by the \$130.00 petition fee (37 CFR 1.17(h)). If the petition states that the application is entitled to a filing date, a request for a refund of the petition fee may be included in the petition. Petitions should be mailed to: Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

- The application was deposited without drawings. 35 U.S.C. 113 (first sentence) requires a drawing "where necessary for the understanding of the subject matter sought to be patented." Applicant should reconsider whether the drawings are necessary under 35 U.S.C. 113 (first sentence)

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE .

Attorney Docket **P1365R2C1**
PATENT**EV 351 923 152 US:** Express Mail Number**August 26, 2003:** Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**NON-PROVISIONAL APPLICATION TRANSMITTAL UNDER 37 CFR 1.53(b)**

Transmitted herewith for filing is a non-provisional patent application:

Inventor(s) (or Application "Identifier"):

Daniel J. Burdick,
Thomas R. Gadek,
James C. Marsters,
Robert S. McDowell,
David Oare,
Mark Reynolds,
Mark S. Stanley, and
Kenneth J. WeeseTitle: **ANTAGONISTS FOR TREATMENT OF CD11/CD18 ADHESION RECEPTOR MEDIATED DISORDERS****1. Type of Application**

- ☐ This application is for an original, non-provisional application.
- ☐ This is a non-provisional application claiming priority to provisional application no. ___, filed ___, the entire disclosure of which is hereby incorporated by reference.
- ☒ This is a continuation application claiming priority under 35 U.S.C. § 120 to application Serial Number 09/646,330, filed September 14, 2000 and to International Patent Application Serial Number PCT/US99/06410, filed March 24, 1999, and under 35 U.S.C. § 119(e) to provisional application Serial Number 60/079,732, filed March 27, 1998, the entire disclosures of which are hereby incorporated by reference.

2. Papers Enclosed Which Are Required For Filing Date Under 37 CFR 1.53(b) (Non-provisional)

172 pages of specification
50 pages of claims
1 page(s) of abstract
0 sheet(s) of drawings
☐ formal ☐ informal

P1365R2C1

Page 2 of 4

3. Declaration or Oath*(for new and CIP applications; also for Cont./Div. where inventor(s) are being added)*

___ An executed declaration of the inventor(s) ☐ is enclosed ☐ will follow.

(for Cont./Div. where inventorship is the same or inventor(s) being deleted)

x A copy of the executed declaration/oath filed in the prior application is enclosed (37 CFR 1.63(d)).

(for Cont./Div. where inventor(s) being deleted)

___ A signed statement is attached deleting inventor(s) named in the prior application (see 37 CFR 1.63(d)(2) and 1.33(b)).

4. Assignment*(for new and CIP applications)*

___ An Assignment of the invention to GENENTECH, INC. ☐ is enclosed with attached Recordation Form Cover Sheet ☐ will follow.

(for cont./div.)

x The prior application is assigned of record to Genentech, Inc.

5. Amendments (for continuation and divisional applications)

___ Cancel in this application original claims ___ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

___ A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claim in the prior application.)

P1365R2C1

Page 3 of 4

6. Fee Calculation (37 CFR 1.16)

The fee has been calculated as follows:

CLAIMS FOR FEE CALCULATION					
Number Filed		Number Extra		Rate	Basic Fee 37 CFR 1.16(a)
					\$750.00
Total Claims	8	- 20 =	0	X \$18.00	\$0.00
Independent Claims	2	- 3 =	0	X \$84.00	\$0.00
Multiple dependent claim(s), if any				+ \$280.00	\$0.00
Filing Fee Calculation					\$750.00

7. Method of Payment of Fees

The Commissioner is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$750.00. A duplicate copy of this transmittal is enclosed.

8. Authorization to Charge Additional Fees

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR §1.16 and 1.17, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this transmittal is enclosed.

9. Additional Papers Enclosed

- ☐ Information Disclosure Statement (37 CFR §1.98) w/ PTO-1449 and citations
- ☐ Submission of "Sequence Listing", computer readable copy, certificate re: sequence listing, and/or amendment pertaining thereto for biological invention containing nucleotide and/or amino acid sequence.
- ☐ A new Power of Attorney or authorization of agent.
- ☒ Other: Limited Recognition Under 37 CFR § 10.9(b)*

10. Maintenance of Copendency of Prior Application (for continuation and divisional applications)

[This item must be completed and the necessary papers filed in the prior application if the period set in the prior application has run]

- ☒ A petition, fee and/or response has been filed to extend the term in the pending prior application until August 26, 2003
- ☒ A copy of the petition for extension of time in the *prior* application is attached.

P1365R2C1

Page 4 of 4

11. Correspondence Address:


X Address all future communications to:

Attn: David W Evans
Customer No: 09157

Respectfully submitted,
GENENTECH, INC.

Date: August 26, 2003

By:


David W Evans

Reg No. *

Telephone No. (650) 1739

CUSTOMER NO: 09157

1 DNA Way
South San Francisco, CA 94080-4990
Facsimile No.: (650) 95209881

*A copy of a document pursuant to 37 CFR §10.9(b) is attached as proof of the authorization of the above to prosecute the attached application.
The original of this document is on file in the Office of Enrollment and Discipline.

P1365R2C1

ANTAGONISTS FOR TREATMENT OF CD11/CD18 ADHESION RECEPTOR MEDIATED DISORDERS

Related Applications

This is a continuation application claiming priority under 35 U.S.C. § 120 to application Serial Number 09/646,330, filed September 14, 2000 and to International Patent Application Serial Number PCT/US99/06410, filed March 24, 1999, and under 35 U.S.C. § 119(e) to provisional application Serial Number 60/079,732, filed March 27, 1998, the entire disclosures of which are hereby incorporated by reference.

Field of the Invention

This invention relates to methods and therapeutic compositions for treating mammals, preferably humans, who suffer from or are susceptible to (CD11/CD18) adhesion receptor mediated disorders, especially leukocyte LFA-1 mediated disorders. In particular, it relates to methods for ameliorating or modulating immune responses such as those caused by inflammation, autoimmune responses and host-graft rejection, as exemplified by psoriasis, rheumatoid arthritis, asthma, multiple sclerosis, rejection following transplanted grafts and the like.

Background of the Invention

Inflammation

Human peripheral blood is composed principally of red blood cells, platelets and white blood cells or leukocytes. The family of leukocytes are further classified as neutrophils, lymphocytes (mostly B- and T-cell subtypes), monocytes, eosinophils and basophils. Neutrophils, eosinophils and basophils are sometimes referred to as "granulocytes" or "polymorphonuclear (PMN) granulocytes" because of the appearance of granules in their cytoplasm and their multiple nuclei. Granulocytes and monocytes are often classified as "phagocytes" because of their ability to phagocytose or ingest micro-organisms and foreign mater referred to generally as "antigens". Monocytes are so called because of their large single nucleus and these cells may in turn become macrophages. Phagocytes are important in defending the host against a variety of infections and together with lymphocytes are also involved in inflammatory disorders. The neutrophil is the most common leukocyte found in human peripheral blood followed closely by the lymphocyte. In a microliter of normal human peripheral blood, there are about 6,000 leukocytes, of which about 4,000 are neutrophils, 1500 are lymphocytes, 250 are monocytes, 150 are eosinophils and 25 are basophils.

During an inflammatory response peripheral blood leukocytes are recruited to the site of inflammation or injury by a series of specific cellular interactions (see Fig. 1). The initiation and maintenance of immune functions are regulated by intercellular adhesive interactions as well as signal transduction resulting from interactions between leukocytes and other cells. Leukocyte adhesion to vascular endothelium and migration from the circulation to sites of inflammation is a critical step in the inflammatory response (Fig. 1). T-cell lymphocyte immune recognition requires the interaction of the T-cell receptor with antigen (in combination with the major histocompatibility complex) as well as adhesion receptors, which promote attachment of T-cells to antigen-presenting

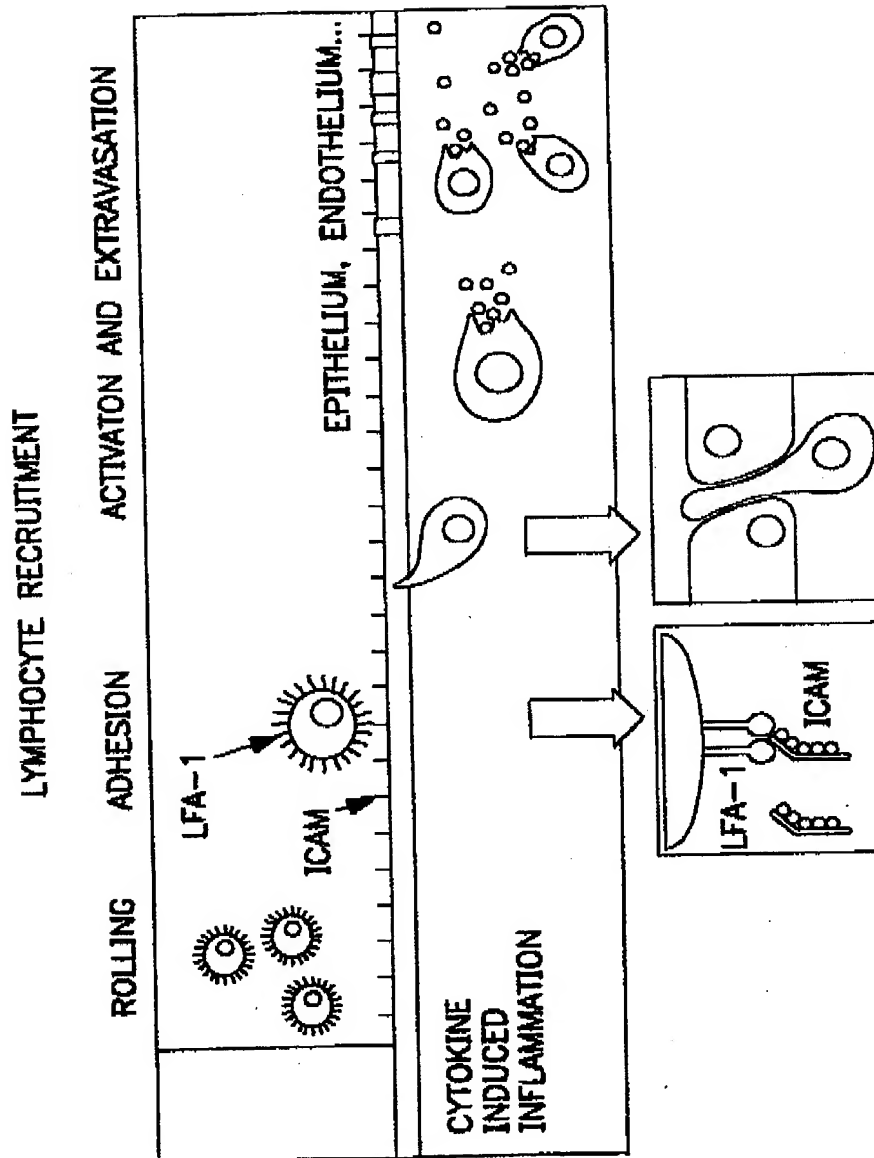


FIG. 1

Human ICAM-1:LFA-1 Receptor Binding Assay

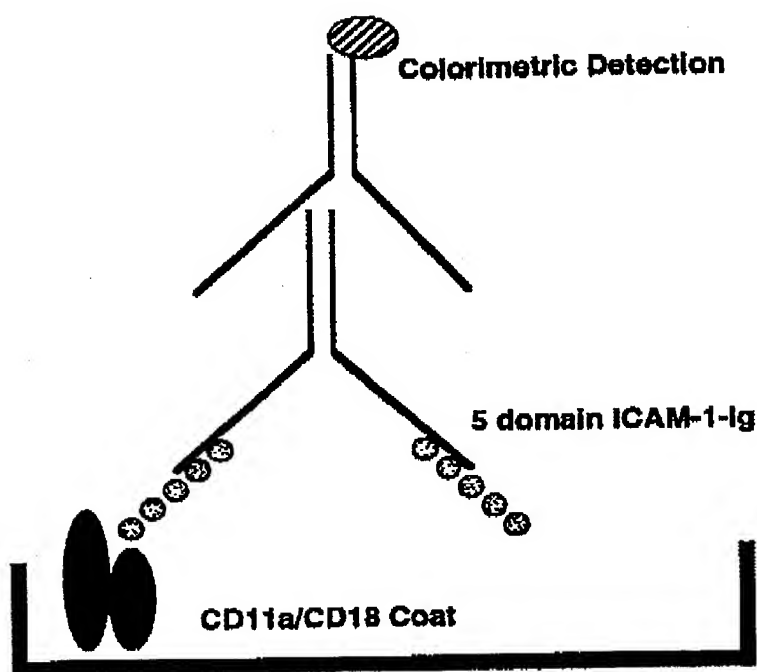


FIG. 2

Human T-cell Adhesion Assay

Colorimetric Detection

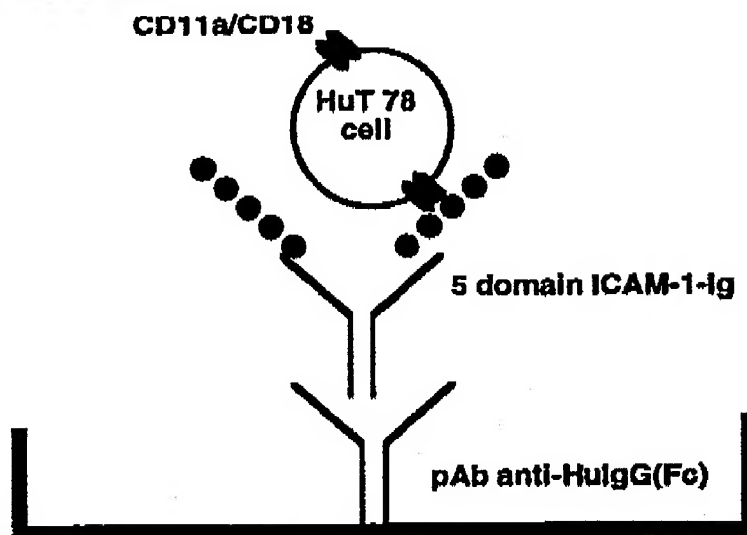


FIG. 3

Human One Way Mixed Lymphocyte Response

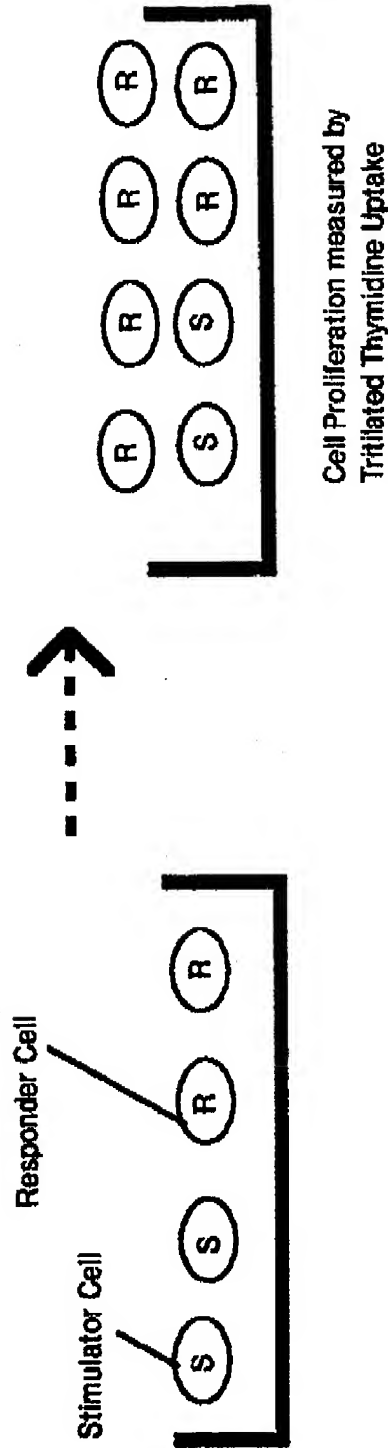
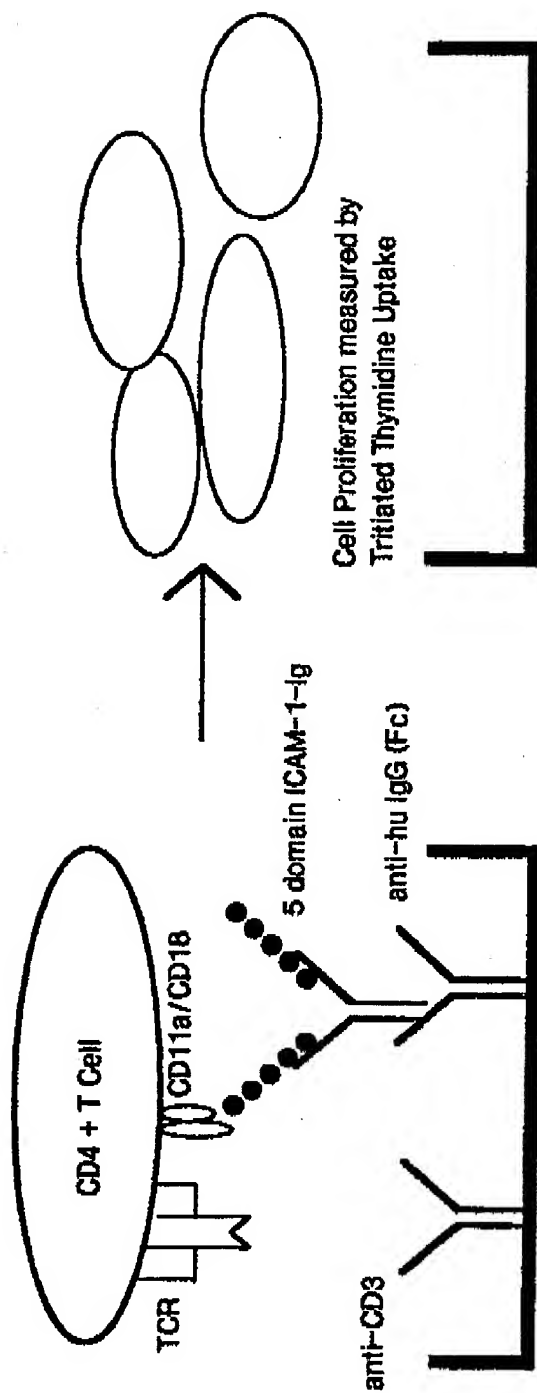


FIG. 4



Coat anti-Fc 2 ug/ml & anti-CD3 .07ug/ml overnight
(50 ul ea.)

Capture 5dICAM-Ig 17 ng/ml (100ul)

Culture 72 hours, pulse cells last 6 hours

FIG. 5

**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATES PATENT AND TRADEMARK OFFICE**

LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

David Evans is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of Genentech, Inc. to prepare and prosecute patent applications in which Genentech, Inc. is the assignee of record of the entire interest. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) David Evans ceases to lawfully reside in the United States, (ii) David Evans's employment with Genentech, Inc. ceases or is terminated, or (iii) David Evans ceases to remain or reside in the United States on an H1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the United States Patent and Trademark Office.

Expires: May 1, 2004



Harry L. Moatz
Director of Enrollment and Discipline